



Docket No. 64081/JPW/AJM/MVM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Bernard F. Erlanger and Bi-Xing Chen  
Serial No.: 10/618,179 Examiner: G.M. Shameem  
Filed : July 11, 2003 Art Unit: 1626  
For : COMPOSITIONS AND METHODS FOR THE INTRACELLULAR  
DELIVERY OF ANTIBODIES

1185 Avenue of the Americas  
New York, New York 10036  
January 13, 2005

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the PTO-1449 form attached hereto as **Exhibit A**. Copies of these references are attached hereto as **Exhibits 1-18**, respectively.

1. U.S. Provisional Application No. 60/395,363, filed July 11, 2002, on behalf of Bernard F. Erlanger et al. (**Exhibit 1**);
2. U.S. Provisional Application No. 60/471,113, filed May 16, 2003, on behalf of Bernard F. Erlanger et al. (**Exhibit 2**);
3. PCT International Application No. PCT/US2003/021842, filed July 11, 2003, International Publication No. WO 2004/030610 A2, published April 15, 2004, on behalf of The Trustees of Columbia University in the City of New

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York (**Exhibit 3**);

4. Avrameas, A. et al. (1998) "Polyreactive anti-DNA monoclonal antibodies and a derived peptide as vectors for the intracytoplasmic and intranuclear translocation of macromolecules," *Proc. Natl. Acad. Sci. USA* 95: 5601-5606 (**Exhibit 4**);
5. Awwad, M. et al. (1994) "Modification of monoclonal antibody carbohydrates by oxidation, conjugation, or deoxymannojirimycin does not interfere with antibody effector functions," *Cancer Immunol. Immunother.* 38: 23-30 (**Exhibit 5**);
6. Braden, B.C. et al. (2000) "X-ray crystal structure of an anti-Buckminsterfullerene antibody Fab fragment: Biomolecular recognition of C<sub>60</sub>," *Proc. Natl. Acad. Sci. USA* 97: 12193-12197 (**Exhibit 6**);
7. Buschle, M. et al. (1997) "Transloading of tumor antigen-derived peptides into antigen-presenting cells," *Proc. Natl. Acad. Sci. USA* 94: 3256-3261 (**Exhibit 7**);
8. Chen, B.-X. et al. (1998) "Antigenicity of fullerenes: Antibodies specific for fullerenes and their characteristics," *Proc. Natl. Acad. Sci. USA* 95: 10809-10813 (**Exhibit 8**);
9. Fawell, S. et al. (1994) "Tat-mediated delivery of heterologous proteins into cells," *Proc. Natl. Acad. Sci. USA* 91: 664-668 (**Exhibit 9**);

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10. Koren, E. et al. (1995) "Murine and human antibodies to native DNA that cross-react with the A and D SnRNP polypeptides cause direct injury of cultured kidney cells," *J. Immunol.* 154: 4857-4864 (**Exhibit 10**);
11. Lewin, M. et al. (2000) "Tat peptide-derivatized magnetic nanoparticles allow in vivo tracking and recovery of progenitor cells," *Nature Biotechnology* 18: 410-414 (**Exhibit 11**);
12. Lundberg, M. et al. (2001) "Is VP22 nuclear homing an artifact?," *Nature Biotechnology* 19: 713 (**Exhibit 12**);
13. Ma, J. et al. (1991) "Antibody penetration of viable human cells. I. Increased penetration of human lymphocytes by anti-RNP IgG," *Clin. Exp. Immunol.* 84: 83-91 (**Exhibit 13**);
14. Mitchell, D.J. et al. (2000) "Polyarginine enters cells more efficiently than other polycationic homopolymers," *J. Peptide Res.* 56: 318-325 (**Exhibit 14**);
15. Rodwell, J.D. et al. (1986) "Site-specific covalent modification of monoclonal antibodies: In vitro and in vivo evaluations," *Proc. Natl. Acad. Sci. USA* 83: 2632-2636 (**Exhibit 15**);
16. Rothbard, J.B. et al. (2000) "Conjugation of arginine oligomers to cyclosporin A facilitates topical delivery and inhibition of inflammation," *Nature Medicine* 6: 1253-

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1257 (**Exhibit 16**);

17. Sutton, B.J. et al. (1983) "The three-dimensional structure of the carbohydrate within the Fc fragment of immunoglobulin G," *Biochem. Soc. Trans.* 11: 130-132 (**Exhibit 17**); and

18. Wender, P.A. et al. (2000) "The design, synthesis, and evaluation of molecules that enable or enhance cellular uptake: Peptoid molecular transporters," *Proc. Natl. Acad. Sci. USA* 97: 13003-13008 (**Exhibit 18**).

The subject application claims priority of U.S. Provisional Application No. 60/395,363, filed July 11, 2002, and U.S. Provisional Application No. 60/471,113, filed May 16, 2003, of which a copy of each is attached hereto as **Exhibits 1** and **2**, respectively.

PCT International Application No. PCT/US2003/021842, filed July 11, 2003 (attached hereto as **Exhibit 3**) also claims priority of above-listed U.S. Provisional Application No. 60/395,363, filed July 11, 2002, and U.S. Provisional Application No. 60/471,113, filed May 16, 2003 and is the foreign counterpart of the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in

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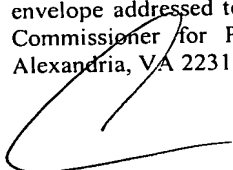
connection with the filing of this Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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Alan J. Morrison  
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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Alan J. Morrison  
Reg. No. 37,399

1/13/03-  
Date

**U. S. Department of Commerce**  
**Patent and Trademark Office**

<b>Application Number</b>	10/618,179
<b>Filing Date</b>	July 11, 2003
<b>First Named Inventor</b>	Bernard F. Erlanger
<b>Art Unit</b>	1626
<b>Examiner Name</b>	G.M. Shameem
<b>Attorney Docket No.</b>	64081/JPH/AJM/MVM

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DATE CONSIDERED

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Exhibit A

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Application Number	10/618,179
		Filing Date	July 11, 2003
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		First Named Inventor	Bernard F. Erlanger
		Art Unit	1626
		Examiner Name	G.M. Shameem
		Attorney Docket No.	64081/JFW/AJM/MVM

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	4	Avrameas, A. et al. (1998) "Polyreactive anti-DNA monoclonal antibodies and a derived peptide as vectors for the intracytoplasmic and intranuclear translocation of macromolecules," <i>Proc. Natl. Acad. Sci. USA</i> 95: 5601-5606;	
	5	Awwad, M. et al. (1994) "Modification of monoclonal antibody carbohydrates by oxidation, conjugation, or deoxymannojirimycin does not interfere with antibody effector functions," <i>Cancer Immunol. Immunother.</i> 38: 23-30;	
	6	Braden, B.C. et al. (2000) "X-ray crystal structure of an anti-Buckminsterfullerene antibody Fab fragment: Biomolecular recognition of C <sub>60</sub> ," <i>Proc. Natl. Acad. Sci. USA</i> 97: 12193-12197;	
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	14	Mitchell, D.J. et al. (2000) "Polyarginine enters cells more efficiently than other polycationic homopolymers," <i>J. Peptide Res.</i> 56: 318-325;	
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SIGNATURE

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\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a checkmark here if English language Translation is attached.

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	16	Rothbard, J.B. et al. (2000) "Conjugation of arginine oligomers to cyclosporin A facilitates topical delivery and inhibition of inflammation," <i>Nature Medicine</i> 6: 1253-1257;	
	17	Sutton, B.J. et al. (1983) "The three-dimensional structure of the carbohydrate within the Fc fragment of immunoglobulin G," <i>Biochem. Soc. Trans.</i> 11: 130-132; and	
	18	Wender, P.A. et al. (2000) "The design, synthesis, and evaluation of molecules that enable or enhance cellular uptake: Peptoid molecular transporters," <i>Proc. Natl. Acad. Sci. USA</i> 97: 13003-13008.	

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